

REMARKS

Upon entry of the foregoing amendment, claims 1-4 and 6-16 are pending. Claims 1-3, 6, 7, 10, 13 and 16 remain withdrawn from consideration as being directed to a non-elected invention. Claims 4, 8, 9, 11, 12, 14 and 15 are under examination.

Claim 5 is canceled without prejudice or disclaimer of the canceled subject matter. Applicants reserve the right to pursue any canceled subject matter in one or more continuing or divisional applications.

Claims 4, 8, 11, 12 and 14 are currently amended.

Claim 4, structure 6, is amended to show the pentavalent carbon as a tetravalent carbon. Support for the amendments to structure 6 of claim 4 is found, for example, in original claim 4, structure 6; and elsewhere throughout the specification. Structures 1, 6, 11 and 16 are also amended to remove multiple hyphens as requested by the Examiner.

Claim 8 is amended to correct a grammatical error.

Claims 11 and 12 are amended to recite correct claim dependency and overcome the rejection under 35 U.S.C. § 112, second paragraph. Claim 12 has been recast and support for the amendments to claim 12 is found, for example, in original claim 16 (showing support for “composition” because the phrase “a vaccine comprising at least one compound”); and elsewhere throughout the specification.

Claim 14 is amended to more clearly claim the subject matter. Support for the amendments to the claim are found, for example, in original claim 14, and page 72 of U.S. published patent application no. 2002/0151473 [‘473]¹ (the patent publication of the instant application). Certain subject matter has been cancelled from claim 14 without prejudice or disclaimer. Applicants reserve the right to pursue any cancelled subject matter in one or more continuing or divisional applications.

This amendment is not believed to introduce new matter and entry is respectfully requested.

¹ Citation by the Examiner to the published patent application.

REJECTIONS

A. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 14 and 15 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter not described in the specification. The rejection is respectfully traversed. Claim 14 is newly amended herein.

The Office argues claim 14 has two interpretations, one of which is that uninfected mammals can be therapeutically treated. Office Action at 2. The Office notes that while Applicants have shown that one or more peptides of the invention can inhibit viral replication *in vitro* (see, for example, page 72 of the '473 publication), the obtained experimental results are not indicative of treatment of uninfected mammals at risk for the disease. The Office concludes that in view of the absence of working examples which would show the skilled artisan how to prevent HIV infection and given the unpredictability in the art, "undue experimentation" would be required to prevent HIV infection.

Without acquiescing to the propriety of the rejection, the phrase "at risk for" is deleted from claim 14. Claim 14 is further amended to more clearly claim the invention. The amendments to claim 14 are believed to address the Examiner's concerns and overcome the rejection. In view of the amendments to claim 14, claims 14 and 15 are believed to be in condition for allowance. Reconsideration and withdrawal of the rejection is respectfully requested.

B. REJECTION OF CLAIM 8

Claim 8 is objected to on grammatical grounds (the "a" should be "an"). Claim 8 is newly amended herein to correct the grammatical error. Reconsideration and withdrawal of the rejection is respectfully requested.

C. REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 4, 5, 8, 9, 11, 12 and 14 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter Applicants regard as the invention. The rejections are respectfully traversed. Claim 5 is canceled.

1. Claim 4 is rejected because structure 6 of claim 4 contains a pentavalent carbon. In reply, structure 6 of claim 4 is amended to correctly show the carbon as a tetravalent carbon.

2. Claim 4 is also allegedly indefinite because the “Z” is surrounded by differing numbers of hyphens and dashes. The Office suggests using a single horizontal line for purposes of clarity. Applicants disagree with the Office conclusion that the presence of hyphens and dashes renders the structures unclear. However, in order to facilitate prosecution towards allowance and issue, claim 4 structures 1, 6, 11 and 16 are rewritten using a single horizontal line as suggested by the Office.

3. Claim 8 is allegedly vague and unclear for making reference to the form “gabcde,” and “defgab.” The rejection is respectfully traversed. Contrary to the position of the Examiner, the specification clearly and unambiguously explains the meaning of the phrases. *See*, for example, specification page 6, line 4 through line 18; page 75, lines 18-24; and elsewhere throughout the specification. The amino acid 633 or its corresponding amino acid in the homolog, consensus or variant sequence is assigned position a of a repeating “abcdefg” assignment. The term “abcdefg” is a sequence “reference aid.” The reference aide is a means of assigning amino acids in a sequence a position in the internal sequence of a constrained peptide. The heptad assignment is repeatedly applied throughout the sequence until all amino acid residues in the sequence of interest have been assigned one of a-g. Claim 8 recites that amino acid 633 is assigned the “a” position, thus permitting the following amino acids in the protein sequence to be given a position identifier of one of a-g.

4. Claim 9 is rejected. Applicants traverse the rejection. The focus of the

rejection is not clear from the Office Action. Claim 9 depends from claim 8, which depends from claim 4. Claim 9 specifically recites that when S is absent, S' is present. "S" finds support in claim 4. As the Office is aware, a dependent claim contains the elements of the claims from which it depends. Because it is clear when S' is present, Applicants assert claim 9 is clear on its face.

5. Claims 11, 12 and 14 are rejected for depending from non-elected claim 10. In reply, claims 11, 12 and 14 are amended to depend from claim 8, thus overcoming the rejection.

6. Claim 11 is rejected allegedly because it is not readily apparent which sequences from Figures 16A-16G are to be included or excluded. Applicants disagree with the Office conclusion. Claim 11 specifically recites sequences as shown in Figures 16A-16G and thus, in fact, recites the most "relevant" information.

7. Claim 12 is rejected for allegedly not being properly subgeneric to claim 8 or 10. The rejection is respectfully traversed. Claim 12 is recast to depend from claim 8, and as amended, is believed to be free of the rejection.

8. Claim 14 is rejected for allegedly reciting an embodiment claiming treatment of a mammal at risk for HIV. Without discussing the merits of the rejection, claim 14 is amended to recite treatment of a mammal infected with HIV.

In view of the amendments to the claims, reconsideration and withdrawal of all rejections under 35 U.S.C. § 112, second paragraph, is respectfully requested.

D. REJECTIONS UNDER 35 U.S.C. § 102(b)

1. Claim 11 is rejected under 35 U.S.C. § 102(b) as being anticipated by Bhatnagar (WO 92/09625). The rejection is respectfully traversed. Bhatnagar does not anticipate claim 11 for at least the following reasons.

According to the Office, Bhatnagar discloses (page 26) cyclic peptides having two cysteines in a disulfide linkage. The Office argues that the sequence in Figures 16A-G allegedly do not limit the claims because 100% of the amino acids can be replaced with

other amino acids. The Office further argues that claim 10 encompasses peptides cyclic by virtue of disulfide bonds.

In reply to the Office rejection, claim 11 is newly amended herein to depend solely from claim 8. Thus, the Office comments regarding claim 10 are no longer relevant.

Contrary to the position of the Office, Bhatnagar does not anticipate claim 11. As the Office is aware, a reference must teach each and every element as set forth in the claim in order to anticipate. (“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Bhatnagar discloses a β -turn tetrapeptide or mimic thereof, wherein X and Y are groups which provide a means to restrict the stereochemical structure of ABCD. Bhatnagar thus discloses a cyclic peptide comprising a sequence of 4 amino acids constrained through sulfide bonds formed by amino acids of the amino acid sequence. In contrast, the compounds of the present invention are cyclized by intramolecularly reacting the side chain amide bond forming substituents flanking the internal amino acid sequence to form an alpha helical peptide (*See*, for example, specification page 75, lines 18-24, and elsewhere throughout the specification).

As the Office is aware, “An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the art.” *ATD Corp. V. Lycall, Inc.*, 159 534, 48 USPQ2s 1321 (Fed. Cir. 1998). And, “Anticipation under Section 102 can be found only if a reference shows exactly what is claimed; where there are differences between the reference disclosures and the claim, a rejection must be based on obviousness under Section 103.” *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). As the Office is aware, a dependent claim contains the elements of the claims from which it depends. Bhatnagar does not teach compounds having identical structural elements to claim 4 structures 1, 6, 11 and 16. Thus, because Bhatnagar does not disclose forming helical peptides having the identical structural

characteristics of the peptides as claimed, Bhatnagar does not and cannot anticipate claim 11, dependent from claim 4.

In view of the foregoing arguments and amendments to the claims, reconsideration and withdrawal of the rejection is respectfully requested.

2. Claim 11 is rejected under 35 U.S.C. § 102(b) as being anticipated by Jackson (*J Am Chem Soc* 113, 9391, 1991). The rejection is respectfully traversed. Jackson does not anticipate claim 11 for at least the following reasons.

According to the Office, Jackson allegedly discloses cyclic peptides containing the sequence: XKAAAAX where X represents 2-amino-6-mercaptohexanoic acid, and wherein the thiol groups are bonded together in disulfide linkage.

However, as the Office is aware, “An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed and that its existence was recognized by persons of ordinary skill in the art.” *ATD Corp. V. Lycall, Inc.*, 159 534, 48 USPQ2s 1321 (Fed. Cir. 1998). And, “Anticipation under Section 102 can be found only if a reference shows exactly what is claimed; where there are differences between the reference disclosures and the claim, a rejection must be based on obviousness under Section 103.” *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). Jackson does not teach compounds having identical structural elements to claim 4 structures 1, 6, 11 and 16. Ad the Office is aware, a dependent claim contains the elements of the claims from which it depends. Thus, because Jackson does not disclose forming helical peptides having the identical structural characteristics of the peptides as claimed, Jackson does not, and cannot, anticipate claim 11, dependent from claim 4.

The Office also argues the explanation over Bhatnagar applies as well. However, Bhatnagar does not anticipate claim 11 for reasons discussed above and those arguments are incorporated herein in their entirety.

In view of the foregoing arguments and amendments to the claims, reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, Applicants respectfully request a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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